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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/045,674	LADNER ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *227-234,240,243 and 248-262* is/are pending in the application.

4a) Of the above claim(s) *248-262* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *227-234,240 and 243* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/07; 12/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection (e.g., see 12/11/06 Response). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/24/07 has been entered. Claims 117-226 were pending. Applicants canceled claims 117-226 and added claims 227-248 in the 12/11/06 Response. Applicants then additionally added claims 249-262 and canceled claims 235-239, 241, 242, and 244-247 in the 7/24/07 Response. Claims 227 and 248 were also amended in that response. Therefore, claims 227-234, 240, 243, and 248-262 are currently pending.

In addition, claims 249-262 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected Group III. This issue was addressed in the 7/16/07 non-compliance letter. Furthermore, newly submitted claim 248 is also directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 248 contains an undefined linker attached to M13 gene III, which does not fall within the scope of a protein and/or library of proteins. The linker could be composed of any material including the non-elected Group III phage particle. In addition, the gene III DNA is patentably distinct from the protein because it is made from nucleotides rather than amino acids and can be separately classified as such. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original

presentation for prosecution on the merits. Accordingly, claim 248 (in addition to claims 249-262) is also withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Therefore, claims 227-234, 240, and 243 are examined on the merits.

Withdrawn Objections/Rejections

2. All outstanding rejections and/or objections are withdrawn in view of Applicants' cancellation of claims 117-226. The objection to the abstract is also withdrawn in view of applicants' 12/11/06 submission.

New Rejections

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 227-234, 240, and 243 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Claims 227-234, 240, and 243 were added or amended in the 7/24/07 response. However, applicant did not show where support for these amendment(s) and/or addition(s) can be found in the specification. Specifically, Applicants' current claim read

on "any" library of peptides, polypeptides or proteins. That is, to the extent that Applicants' claimed library no longer represents VH CDR regions such broadened scope represents new matter. For example, Applicants' claims are drawn to a library of peptides, polypeptides or proteins encoded by DNA sequences "comprising" sequences encoding VH CDR1 and CDR2 (e.g., see independent claim 227). Use of open-ended "comprising" language in this case broadens the claimed scope to read on "any" library of peptides, polypeptides, or proteins whether those library members were encoded by a VH CDR1 or CDR2 region or not. For instance, a library of genes (e.g., X, Y and Z) that also contain separate encoding VH CDR1 and CDR2 regions would produce proteins X, Y, and Z "in addition" to the VH CDR1 and CDR2 upon expression (e.g., 5'-X-VH-CDR1-3' or 5'-Y-VH-CDR2-3'). However, each member of the library does not need to be encoded by the "entire" DNA sequence. Thus, the claims read on a library of undefined X, Y, and Z peptides, polypeptides or proteins. Likewise, the dependent claims similarly fail to further limit these undefined library members because they only provide limitations that further limit the VH CDR portions of the DNA. Thus, Applicants' claimed scope encompasses "any" library of peptides, polypeptides, or proteins as stated above. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02.

Claims Rejections – 35 U.S.C. 102/103

4. Claims 227-234, 240, and 243 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heddle et al. (Heddle, R. J.; Rowley, D.

"Dog immunoglobulins. I. Immunochemical characterization of dog serum, parotid saliva, colostrum, milk and small bowel fluid." *Immunology*, **1975**, *29*, 1, pages 185-195) (of record) as evidenced by Roitt et al. (Roitt, I.; Brostoff, J.; Male, D. Immunology Sixth Edition. New York: Mosby **2001**, page 67-70 and 80) (of record).

Applicants' claims are drawn to a library of peptides, polypeptides or proteins encoded by DNA sequences "comprising" sequences encoding VH CDR1 and CDR2 (e.g., see independent claim 227). Use of open-ended "comprising" language in this case broadens the claimed scope to read on "any" library of peptides, polypeptides, or proteins whether those library members were encoded by a VH CDR1 or CDR2 region or not. For example, a library of genes (e.g., X, Y and Z) that also contain separate encoding VH CDR1 and CDR2 regions would produce proteins X, Y, and Z "in addition" to the VH CDR1 and CDR2 upon expression (e.g., 5'-X-VH-CDR1-3' or 5'-Y-VH-CDR2-3'). However, each member of the library does not need to be encoded by the "entire" DNA sequence. Thus, the claims read on a library of undefined X, Y, and Z peptides, polypeptides or proteins. Likewise, the dependent claims similarly fail to further limit these undefined library members because they only provide limitations that further limit the VH CDR portions of the DNA. Thus, Applicants' claimed scope encompasses "any" library of peptides, polypeptides, or proteins as stated above.

For ***claims 227-234, 240, and 243***, Heddle et al. disclose a library of proteins comprising a collection of members of an antibody family, which would read on a library of "any" proteins and thus anticipate the claimed invention (e.g., see page 190, Table 3

wherein a library of proteins is disclosed comprising a collection of IgA, IgM and IgG members of a dog immunoglobulin family).

The libraries of Heddle et al. meet all of the limitations of the claimed library (see above) except for the product-by-process limitations (e.g., produced by an encoding process instead of say an entirely synthetic process as in claim 227, produced from a B cell isolated from a blood sample of a patient as in dependent claim 232, etc.) and thus would either anticipate or render obvious the claimed library because the process of Heddle et al. produce the same or a substantially similar product (see above). See MPEP § 2113, "'[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.' *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either 35 U.S.C. 102 or 35 U.S.C. 103 is eminently fair and acceptable. PTO is not equipped to make and then compare products. *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
July 30, 2007

JON EPPERSON
PRIMARY EXAMINER